



August 3, 2023

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**By ECF**

Hon. Ann M. Donnelly, U.S.D.J.  
U.S. District Court, Eastern District of New York  
225 Cadman Plaza East,  
Brooklyn, NY 11201

**Re: Gilead Sciences et al. v. Safe Chain Solutions LLC et al.,  
No. 21-cv-4106 (AMD) (RER)**

Dear Judge Donnelley:

Plaintiffs (together, “Gilead”) respectfully submit this letter in response to the Court’s August 1, 2023 Text Order requesting letters “explaining whether Safe Chain’s claim ‘on a purely legal issue’ is more properly made in [a] motion for judgment on the pleadings under Federal Rule of Civil Procedure 12(c),” rather than via a summary judgment motion.

If Safe Chain were truly seeking resolution of a “purely legal issue,” on which Gilead’s claims were exclusively based, a motion pursuant to Rule 12(c) could be appropriate. But despite Safe Chain’s representations to the Court, it is *not* seeking resolution of a purely legal issue. Furthermore, even if the Court were to resolve the issues presented as “purely legal” in Safe Chain’s favor, Gilead’s claims against Safe Chain would nevertheless survive, thus rendering a Rule 12(c) motion procedurally inappropriate, as well as unhelpful to narrow the case at this stage.

**A. The Issue Raised by Safe Chain Is Not “Purely Legal”**

In its letter, Safe Chain represents that it intends “to seek summary judgment on [Gilead’s] novel theory that inaccurate information on government-required transaction histories (‘pedigrees’) renders otherwise pristine bottles of pills ‘counterfeit’ under the Lanham Act.” ECF No. 1155 at 1. While Safe Chain may wish to re-write history by mischaracterizing its actions and Gilead’s claims, the facts and the law speak for themselves: Safe Chain sold over 28,000 bottles of Gilead-branded products with, at a minimum, falsified pedigrees that concealed their illicit origin. The fraudulent pedigrees were designed to dupe unsuspecting purchasers—and ultimately patients—into thinking they were purchasing genuine Gilead medication from the legitimate supply chain. The Court’s July 31, 2023 Memorandum Decision and Order resolved the exact issue raised by Safe Chain, finding that “[t]he allegations here are that *the pedigrees contained made-up chains of sale* intended to confuse consumers, conceal material differences that would likely be relevant to a consumer’s decision to purchase the drugs, and flout the trademark holder’s quality control standards. *These are classic Lanham Act claims.*” ECF No. 1153 at 15 (emphasis added). That finding, now the law of the case, renders Safe Chain’s request moot.

While absent from its letter to the Court, in its correspondence with Gilead, Safe Chain has clarified that its motion will be based on arguments that (1) the first sale doctrine and (2) the nominative fair use doctrine preclude liability under the Lanham Act. ECF No. 1154 Ex. A

at 1. As to the first sale doctrine, Safe Chain further specifies that they will argue “that neither the quality control nor material difference exception to that doctrine applies.” *Id.* These arguments raise factual issues and mixed questions of law and fact that are inappropriate for resolution via Rule 12(c), or were already resolved by the Court.

“The Quality Control Exception applies when goods do not conform to the trademark holder’s quality control standards.” *Coty Inc. v. Cosmopolitan Cosms. Inc.*, 432 F. Supp. 3d 345, 349 (S.D.N.Y. 2020). In an attempt to overcome the exception, Safe Chain’s proposed Rule 56.1 statement includes several paragraphs purporting to describe Gilead’s quality-control practices. ECF No. 1154 Ex. A ¶¶ 7-15. Thus, Safe Chain’s motion would place at issue multiple broad issues of fact concerning Gilead’s quality control standards and how Safe Chain’s actions—including but not limited to the creation of false pedigrees—failed to conform with and undermined those standards. Of course, this Court has already recognized that “[t]he allegations here are that the pedigrees contained made-up chains of sale intended to . . . flout [Gilead’s] quality control standards.” ECF 1154 at 15.

“The Material Difference Exception applies if [] goods differ in a way that would likely be relevant to a consumer’s decision to purchase them.” *Coty Inc.*, 432 F. Supp. 3d at 350. Again, the Court has already determined that using fraudulent pedigrees to hide the fact that medications were already dispensed to patients before being illegally reintroduced into the drug supply chain renders the products materially different. ECF No. 1153 at 15-17. But even if that were not the law of the case, only a single material difference is required to find a product infringing, and the products sold by Safe Chain are materially different from authentic Gilead products in myriad ways, including among other things their fake pedigrees, missing or counterfeit instructions, and differences caused by the process of purchasing already-dispensed bottles off the street that have been handled by patients and are covered by large, pharmacy-applied patient stickering. All of those factual differences would be raised by Safe Chains’ proposed motion.

Finally, even if the nominative fair use doctrine were applicable here, it can be applied only via a fact-specific inquiry that, among other things, requires an examination of whether there is a “likelihood of confusion” by the use of the plaintiff’s mark, including “whether the defendant did anything,” either by “conduct or language,” to falsely suggest endorsement or otherwise fail to represent “the true or accurate relationship between plaintiff’s and defendant’s products or services.” *Int’l Info. Sys. Sec. Certification Consortium, Inc. v. Security University, LLC*, 823 F. 3d 153, (2d Cir. 2016). Once again, this Court has already held that Gilead’s allegations regarding the use of “made up pedigrees” are sufficient to find “a likelihood of confusion regarding the source of the medications.” ECF No. 1153 at 17 (cleaned up). But even if the Court had not made that finding, to defeat liability under the nominative fair use doctrine, Safe Chain would, among other things, have to prove that it did not “do anything” to cause a likelihood of confusion—which is, of course, a factual issue.

Because the arguments asserted by Safe Chain raise issues of fact, and because the Court already determined Gilead’s allegations are sufficient to overcome Safe Chain’s arguments, neither a Rule 12(c) nor a Rule 56 motion is appropriate at this time. To be clear, Gilead strongly believes it will prevail on its claims at summary judgment on a properly presented, fully developed factual record. But with discovery ongoing, Safe Chain’s proposed motion, whether under Rule 12(c) or 56, would be a waste of resources, especially given the Court’s recent determination that the fraudulent pedigrees at issue in this case present “classic Lanham Act claims.” *Id.* at 15.

**B. Resolution of this Single Issue in Safe Chain’s Favor Would Not Result in a Judgment or Change the Scope of Discovery**

Even if—contrary to the law of the case—the Court were to agree with Safe Chain that *its* fraudulent pedigrees do not create a likelihood of confusion or render the medications it sold materially different, that decision would not result in the dismissal of *any* of Gilead’s claims. This is yet another reason a Rule 12(c) motion would be an inappropriate vehicle to advance the case. “[M]otions under Rule 12(c) must result in a ‘judgment,’ which is defined . . . as ‘a decree and any order from which an appeal lies.’” *Meisels v. Meisels*, 19-cv-4767, 2021 WL 1924186, at \*7 (E.D.N.Y. May 13, 2021). “This definition reflects the historic rule in the federal courts prohibiting piecemeal disposition of litigation.” *Id.* (cleaned up). Where a party’s “request would not result in a judgment, Rule 12(c) is an improper vehicle.” *Id.* at \*8.

Here, as Gilead stated in its prior letter, Gilead’s Lanham Act claims are based on multiple elements of the products Safe Chain sold. *See* Sixth Amend. Compl, ECF No. 1056 ¶¶ 700-792. So even if Safe Chain were to prevail on its already-rejected fraudulent pedigree theory, its proposed motion still would not lead to the dismissal of any of Gilead’s Lanham Act claims against them—a point that Safe Chain conceded in meet-and-confer discussions.

Moreover, Safe Chain does not convincingly argue that dismissing the portion of each claim based on fraudulent pedigrees would materially narrow this case or the parties’ discovery obligations. Safe Chain claims that “98.98% of the allegedly ‘counterfeit’ bottles for which Gilead seeks liability against Safe Chain were genuine Gilead bottles containing genuine Gilead drugs with genuine Gilead caps, labels, and instructions.” ECF No. 1155 at 1. This is simply false, for reasons beyond the fact that medication purchased from patients off the street is not “genuine.” *First*, Safe Chain ignores that it sold bottles without instructions, as well as other material differences resulting from selling bottles that were purchased from patients off the street. *Second*, to support its “math,” Safe Chain argues that of the 1,042 *unsold* bottles (all accompanied by fraudulent pedigrees) Gilead seized from Safe Chain’s warehouse, to date, Gilead has identified 60 that contained the wrong pills or counterfeit foil seals, outserts, or caps. ECF No. 1154 Ex. A ¶¶ 16-17, 23. But Safe Chain ignores that Gilead never inspected **over 28,000** bottles that Safe Chain had *already sold* to pharmacies with fraudulent pedigrees—to be consumed by patients—before Gilead’s seizure.<sup>1</sup> Safe Chain’s assertion that those bottles already dispensed to patients are, in essence, out of the case is wishful thinking at best. Gilead continues to engage in discovery, including with Safe Chain, its co-conspirators, its vendors, and its customers, regarding the counterfeit Gilead-branded products that Safe Chain sold. Simply put, to the extent any legal issues raised by Safe Chain in connection with its proposed motion are not moot, they are dependent on facts still being developed in discovery and are not ripe for further adjudication at this stage.

For all these reasons, Gilead respectfully requests that the Court issue an order stating that any “purely legal” issues raised by Safe Chain are moot; that Gilead need not serve a Rule 56.1 counterstatement; that Safe Chain’s proposed motion would be improper under Rule 12(c); and that Safe Chain cannot file its proposed motion for partial summary judgment at this time, but may file for summary judgment on any issue at the close of discovery.

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<sup>1</sup> Judge Kovner entered the seizure order based on unrefuted evidence that Safe Chain sold numerous counterfeits with the wrong pills in the bottles to pharmacies that were dispensed to patients. *See* ECF No. 2-1.

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Respectfully submitted,

*/s/ Timothy A. Waters*

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cc: All counsel of record (via ECF)